PANDEMIC PROVIDER WEEKLY BROWN BAG

Updated May 3, 2022

Updates

The FDA has approved an amendment to the EUA for Pfizer Tris (Orange and Gray cap) COVID-19 vaccines extending the shelf-life from 9 to 12 months

Printed Manufacturing Date	12-Month Expiray Date		
06/2021	31-May-2022		
07/2021	30-Jun-2022		
08/2021	31-Jul-2022		
09/2021	31-Aug-2022		
10/2021	30-Sep-2022		
11/2021	31-Oct-2022		
12/2021	30-Nov-2022		
01/2022	31-Dec-2022		
02/2022	31-Jan-2023		
03/2022	28-Feb-2023		

^{*}Date of expiration always falls on the last day of the month

Please Note:

- The QR code provided on the Pfizer Pediatric (orange cap) Vaccine carton provides a link to the EUA but does not provide information on expiration dates.
- No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data submitted by the manufacturer to the FDA.
- COVID-19 vaccines authorized under an EUA do not have fixed expiration dates, and expiration dates may be extended as more stability data is collected. Always check <u>Expiry Information for</u> <u>Pfizer COVID-19 Vaccines</u> to obtain the most up-to-date expiration dates for the Pfizer COVID-19 vaccines you have in inventory.

Reminders:

- Do not use Pfizer Tris (Orange and Gray cap) products beyond 12 months from manufacture date.
- Expiration dates for the Pfizer Tris (Orange and Gray cap) products are NOT printed on the vaccine cartons or vials.
- Do not store Pfizer vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

As of <u>4/7/2022</u> Janssen COVID-19 vaccines have been granted a shelf life extension for an additional 3 months. Double check expiration dates for all Janssen lots at https://vaxcheck.jnj/ prior to wasting.

- Check the <u>Janssen website</u> for all lots to determine the most up to date expiration date for storage in the refrigerator
- Can be stored in the refrigerator up to 11 months (2°C and 8°C)
- Link to <u>ADHS J&J Janssen job aid</u>
- Link to <u>CDC J&J Janssen web page</u>

Vaccine Storage

Janssen COVID-19 Vaccine

Refrigerator



- 2.0° C to 8.0° C
- 36.0° F to 46.0° F
- . Store in refrigerator for up to 11 months
- . DO NOT REFREEZE

Dosage



- Each vaccine vial contains 5, 0.5mL doses to be administered
- · No reconstitution required
- Discard any punctured vial held at refrigerator temperatures after 6 hours
- Discard any punctured vial held at room temperature (maximally 25°C/77°F) after 2 hours

Administration



- · Standard needles and syringes
- . Draw 0.5mL and inject intramuscularly (IM)
- Single do:
- For adults 18 and older
- . Not for children
- Can be administered until 11:59 p.m. EST on expiry date. Expiry dates can be verified on the lanssen website

CDC Recommends Additional COVID-19 Vaccine Boosters for Certain Individuals

The CDC expanded eligibility for an additional booster dose for certain individuals who may be at higher risk of severe outcomes from COVID-19. Boosters are safe, and people over the age of 50 can now get an additional booster 4 months after their prior dose to increase their protection further.

The FDA amended the emergency use authorizations as follows:

- A second booster dose of the Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered to individuals 12 years of age and older with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the Moderna COVID-19 Vaccine may be administered at least 4 months after the first booster dose of any authorized or approved COVID-19 vaccine to individuals 18 years of age and older with the same certain kinds of immunocompromise.

COVID-19 Vaccination Schedule for Primary and Booster Doses

COVID-19 Vaccination Schedule - for Primary Series in the General Population

Primary series vaccine manufacturer	Age Group	Number of doses in primary series	Number of booster doses	Interval between 1st and 2nd dose	Interval between primary series and booster dose
Pfizer-BioNTech Orange Cap	5-11 years	2	N/A	3 weeks	N/A
Pfizer-BioNTech Purple Cap OR Gray Cap	12 years and older	2	1*	3-8 weeks**	At least 5 months*
<u>Moderna</u>	18 years and older	2	1*	4-8 weeks**	At least 5 months*
<u>Janssen</u>	18 years and older	1	1*	NA	At least 2 months*

^{*}All people ages 12 years and older should receive 1 booster dose of a COVID-19 vaccine. Some adults may receive a second booster dose:

- Adults ages 18-49 years: Those who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive an mRNA COVID-19 booster dose at least 4 months after the Janssen booster dose.
- Adults ages 50 years and older: A second mRNA booster dose could benefit people ages 50 years and older, as they are at increased risk for severe COVID-19. People ages 50 years and older may choose to receive a second booster dose, if it has been at least 4 months after the first booster

**An 8-week interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately to severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

COVID-19 Vaccination Schedule for Primary and Booster Doses

COVID-19 Vaccination Schedule - for People with Moderate or Severe Immunocompromise

Primary Vaccination	Age Group	Number of doses in primary series	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between primary series and booster dose
Pfizer-BioNTech Orange Cap	5-11 years	3	N/A	3 weeks	At least 4 weeks	N/A
Pfizer-BioNTech Purple Cap OR Gray Cap	12 years and older	3	1*	3 weeks	At least 4 weeks	At least 3 months*
<u>Moderna</u>	18 years and older	3	1*	4 weeks	At least 4 weeks	At least 3 months*
<u>Janssen</u>	18 years and older	1 Janssen, followed by 1 mRNA	1*	4 weeks	At least 2 months	N/A*

^{*}People ages 12 years and older may choose to receive a second booster dose using an **age-appropriate** mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose.

As of now, on March 22, 2022, the HRSA COVID-19 Uninsured Program will stop accepting claims for testing and treatment of COVID-19 due to lack of sufficient funds. On April 5, 2022, the program will also stop accepting vaccination claims due to a lack of sufficient funds. For additional information, please see the HRSA COVID-19
Uninsured Program Claims Submission Deadline FAQs and the White House Fact
Sheet.

When is the final deadline to submit claims for reimbursement?

The deadlines to submit claims for each category of service are as follows:

- Testing claims: March 22, 2022, at 11:59 p.m. ET
- Treatment claims: March 22, 2022, at 11:59 p.m. ET
- Vaccine administration claims: April 5, 2022, at 11:59 p.m. ET

Any testing and treatment claims submitted in the Portal after March 22, 2022, will not be adjudicated for payment.

Any vaccine administration claims submitted in the Portal after April 5, 2022, will not be adjudicated for payment.

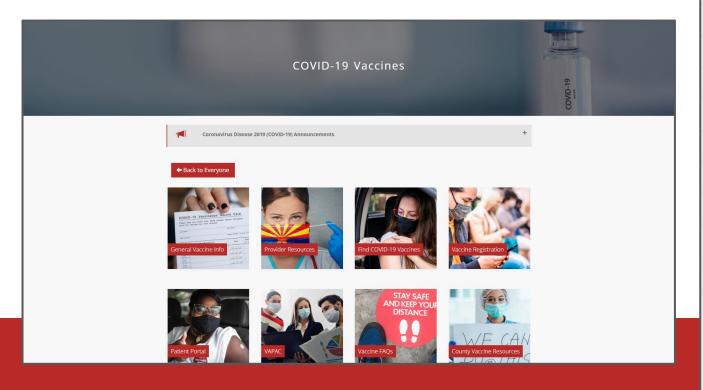
No More LIVE Brown Bag Webinar

(Our LAST live webinar was January 25th 2022)

We will continue to update these slides and post an updated copy of these slides on the <u>COVID-19 provider resources page</u> as needed but we will no longer hold the weekly live webinar.

ADHS COVID-19 Vaccine Website

azhealth.gov/covid19vaccine



COVID-19 Menu

◆COVID-19

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Vacunas en Español

General Vaccine Info

Provider Resources

Find COVID-19 Vaccines

Vaccine Registration

Patient Portal

VAPAC

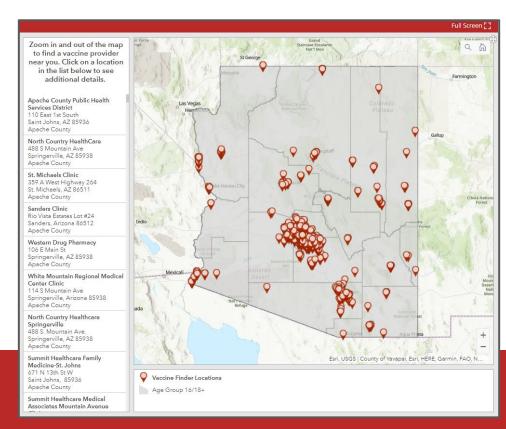
Vaccine FAQs

County Vaccine Resources



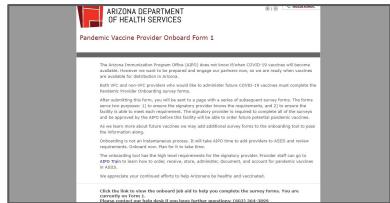
ADHS Find Vaccine webpage <u>azhealth.gov/findvaccine</u>

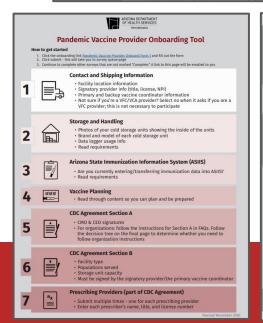
- The locations of vaccination sites
- Filter to sort by vaccine type
- Use the patient portal at <u>podvaccine.azdhs.gov</u> to make an appointment for a relative
- Appointments recommended but no longer required at state-operated sites

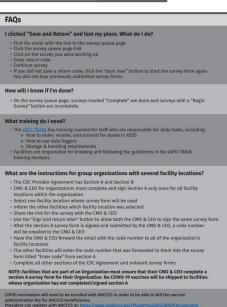


Pandemic Provider Onboarding Start Form

- All facilities must onboard to be able to order/administer COVID-19 vaccines
- <u>Pandemic Vaccine Provider Onboarding Tool</u> Job Aid (bottom right)
- Wait until you're at the facility to onboard so you can upload photos of inside and outside of units
- Read through forms for important requirements
- Note: Per the CDC Agreement, COVID-19 vaccines must be recorded in the vaccine recipient's record, the required information reported to the relevant state, local, or territorial public health authority, and decremented from the inventory within 24 hours of administration.







Required Reporting

- ASIIS
 - o for inventory accounting and dose administration data within 24 hours
 - Required even if you use an EHR, ADHS VMS app, etc.
 - Verify ASIIS Lot Number > Reconciliation page (ASIIS Inventory) numbers should be matched between the quantity on hand and physical inventory columns
 - Vaccine Inventory Management course in AIPO Train
- ArcGIS Survey 123
 - To identify every vaccination events schedule (open or closed) for GIS mapping
- Vaccines.gov/CDC VaccineFinder weekly inventory by Fridays
- Survey as needed for providers who are not using doses ordered in a timely manner
- County surveys as required by your local jurisdiction

Your ASIIS inventory is used by local, state, and federal leaders to make vaccine ordering decisions - It MUST be accurate

COVID-19 Inventory Management Reminders

In order to ensure that provider sites are being good stewards of the COVID-19 vaccines, the CDC has emphasized that each COVID-19 vaccination site should have at most 3-4 weeks of vaccine inventory on hand.

- Place smaller, more frequent orders to avoid stockpiling doses
- Use the data in ASIIS to determine how many doses you use & how many doses are on hand to place an order for an appropriate amount of doses
- Use the <u>ADHS vaccine transfer matchmaker website</u> to request a smaller quantity of doses then can be ordered in ASIIS
- Administered doses must be entered in ASIIS within 24 hours and decremented from the ASIIS inventory
- <u>CDC VaccineFinder (vaccines.gov)</u> inventory must be updated weekly by Friday
- Wasted/Expired Doses must be reported on signed and complete <u>wasted/expired forms</u> weekly

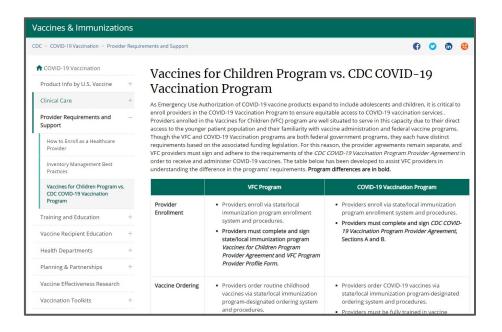
Off-Label Use

Pandemic providers should be aware that they must use COVID-19 vaccines according to FDA and CDC guidance. Use of COVID-19 vaccines outside of FDA and CDC recommendations ("off label") is a violation of the provider agreement.

- Providers may not be covered under PREP Act and therefore not have the immunity from prosecution that the PREP Act provides.
- Recipients of an "off-label" COVID-19 vaccine dose may not be covered by the Countermeasure Injury Compensation Program if they were to have serious adverse events from the vaccine.
- Providers who violate the CDC agreement may not be able to remain as part of CDC programs.
- COVID-19 vaccine administration fees may not be covered if the dose were given "off-label."

CDC Website: VFC vs. COVID-19 Vaccination Programs

- Separate programs with separate agreements
- Distinct requirements for each
- Help VFC providers understand difference between program requirements



<u>Vaccines.gov</u>/CDC VaccineFinder Provider Resources

The "organization email" listed in Section A of the CDC Agreement will get an email from vaccinefinder@auth.castlighthealth.com to sign up

- Weekly reporting by Friday of on-hand inventory quantities is a requirement
- Activating a location to display to the public is optional
- Providers can update display to the public function at any time
- Once COVID-19 vaccine locations are launched in Vaccines.gov, changes show publicly within 24 hours
- Check phone number in provider portal before making site public
- <u>Vaccines.gov</u> homepage patients can find vaccines

• NOTE: If a site that is set to display to the public fails to update inventory within 72 hours, the availability information for each vaccine will display as "Call to confirm" on Vaccines.gov.

COVID-19 Administration Reporting Systems (CARS) Help Desk

- Monday through Friday, 8:00 am to 8:00 pm ET.
- CARS HelpDesk@cdc.gov
- 1-833-748-1979
- Provide PIN when calling



Changes to the Required Temperature Incident Reporting Process for COVID-19
Vaccine Temperature Incidents

The Arizona Immunization Program Office (AIPO) is introducing changes to the required temperature incident reporting process for COVID-19 vaccine temperature incidents. This process is intended to improve incident turnaround times for providers by allowing them to take ownership of the process by following the steps in the Temperature Incident Instructions Checklist to obtain a viability determination from the manufacturer.

This is a required process for reporting all temperature incidents involving COVID-19 vaccines. The AIPO also encourages you to please fill out the survey at the end of the process as we value your feedback.



Daily COVID-19 Vaccine Tasks

Temperature Monitoring

- Twice per day monitor temperatures using the <u>approved</u> <u>data logger</u>
 - Document that you monitored temperatures using the paper temp log
 - Comirnaty/Pfizer ULT <u>Celsius</u> <u>Fahrenheit</u>
 - Refrigerator <u>Celsius</u> <u>Fahrenheit</u>
 - Moderna Freezer Celsius Fahrenheit
 - Document current, min, max, time, and initials
- If there are out of range temperatures, stop using the vaccines and submit an <u>incident report</u> to the AIPO
- Twice per month download and save the data logger data reports
 - Keep the data logger reports readily available for 6
 years
 Submit the data logger reports (in an acceptable file
 format: .xls, .txt, .ltd or .csv) to the AIPO upon request

Take a physical inventory count of doses in the cold storage units

- Compare the physical count to ASIIS lot number reconciliation inventory
- The inventories should be the exact same if doses given are entered properly in ASIIS. If you need to troubleshoot, use this job aid.
- Enter the weekly inventory by Fridays into CDC Vaccines.gov

Document doses administered in ASIIS within 24 hours

 Shipments must be marked "received" in ASIIS prior to administration in order for the doses to decrement from the inventory

If you would no longer like to participate as a pandemic provider please follow these steps

1. Account for all doses in ASIIS

- a. You are responsible for accounting for ALL of the doses shipped to you
- b. Ensure all doses shipped to the facility were <u>received in ASIIS</u>
- c. Ensure all doses administered were decremented from the ASIIS inventory
- d. ASIIS inventory reconciliation screen should be accurate

2. If you still have doses

- a. The doses will need to be transferred to another COVID-19 provider
- b. <u>Transfers must have prior approval in ASIIS</u>
- 3. Enter zero in CDC Vaccines.gov inventory when your inventory is depleted
- 4. Notify ADHS after doses have been accounted for

<u>AIPO Train</u>

- Training on ordering, receiving, and accounting for doses in ASIIS
- Information on data loggers setting up, downloading data
- Onboarding resources
- Mass immunizations

How to Register

- 1. Go to https://aipo.myabsorb.com/?KeyName=PandemicProviders (This link automatically enters the enrollment key)
- 2. Enter required fields
- 3. Select Sign up
- 4. Click email activation link (important)

How to Log In

- 1. Go to https://aipo.myabsorb.com/#/login
- 2. Enter username and password (username will be email address)
- 3. Select Log In

For existing AIPO Train users: Enter enrollment key "PandemicProviders" to access pandemic-specific training

Questions? Email AIPOTrain@azdhs.gov

Administration Fee

- CMS has a toolkit to help health care providers prepare to administer vaccines
- Vaccine doses given to the American people at no cost
- Providers contractually agree to administer a COVID-19 vaccine regardless of an individual's ability to pay and regardless of their coverage status
- May not seek any reimbursement, including through balance billing, from a vaccine recipient
- People without health insurance can get COVID-19 vaccine at no cost
- If you give COVID-19 vaccines to patients who are covered by **AHCCCS** you will need to be enrolled with AHCCCS in order to bill AHCCCS the administration fee
 - o Register with AHCCCS here

Facilities cannot bill patients for the cost or admin fee for COVID-19 vaccines.

CVX Code and CPT Code Resources

- CMS <u>Helpful for Billing</u>
- CDC <u>Helpful for Uploading Data in EHR and ASIIS</u>
- ADHS <u>Arizona HL7 Specific Rules</u>

TAPI - The Arizona Partnership for Immunizations (State immunization coalition)

- COVID-19 Resources
- COVID-19 Vaccine Billing Policy Information
- Resources for immunizations at off-site locations

CDC Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

CDC has issued revised <u>Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations</u> to assist with jurisdictional planning and implementation of satellite, temporary, or off-site vaccination clinics by public and private vaccination organizations.

The guidance is broken down into four categories:

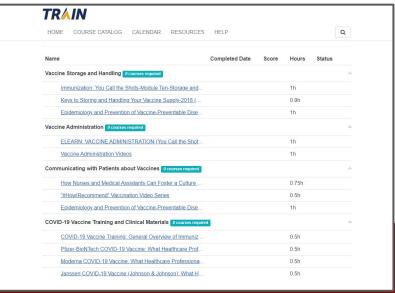
- Planning activities
- Pre-clinic activities
- During the clinic activities
- Post-clinic activities

The guidance also provides information on additional considerations required during the COVID-19 pandemic, including physical distancing, personal protective equipment (PPE), and enhanced sanitation efforts

Training for Healthcare Professionals

- CDC COVID-19 Vaccine Training Modules
- <u>Public Health Foundation Training Plan</u>



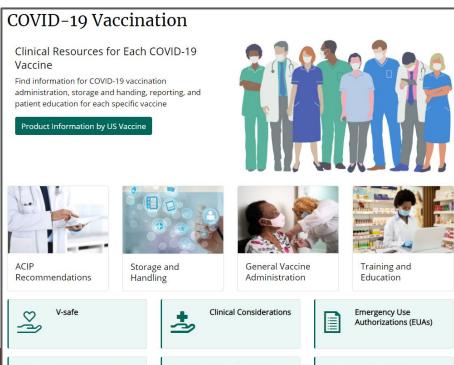


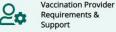
Immunization Action Coalition - immunize.org

- Info on administering vaccines
- Handouts for staff and patients
- "Ask the Experts" page
 - Includes <u>COVID-19 vaccines</u>
- Option to sign up for IAC Express email
 - Weekly email with updates to information and resources



CDC COVID-19 Vaccination Clinical Resources







Vaccination Data & Reporting Systems



Planning & Partnerships

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently

Authorized in the United States

Other resources:

- Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently **Authorized in the United States**
- **COVID-19 Vaccine Administration Errors and Deviations**



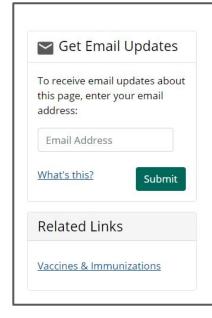


for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

	Pfizer-B	ioNTech	Moderna	Janssen
Age groups	5 through 11 years of age	12 years of age and older	18 years of age and older	18 years of age and older
Vaccine type	ml	RNA	mRNA	Replication-incompetent adenovirus type 26 vector
Dose	10 μg (orange cap)	30 µg (purple cap)	100 µg (primary series and additional primary dose) 50 µg (booster dose)	5×10 ¹⁰ viral particles
Dosage (volume)	0.2 mL	0.3 mL	0.5 mL (primary series and additional primary dose) 0.25 mL (booster dose)	0.5 mL
Number of doses in primary series		2	2	1
Interval between primary series doses	3 weeks	(21 days)	1 month (28 days)	N/A
Additional (3rd) primary dose for moderately or severely immunocompromised persons	Currently not authorized for this age group	Recommended at least 28 days after the 2nd dos severely immunocompromised people 12 years of age and older futtps://www.cdc.gox.covid-19-vaccines-us.html@considerations-cov Use the same vaccine product as the primary ser	Not authorized as an additional primary dose. See information below about a booster dose	
Booster dose	Currently not authorized for this age group	the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose or the additional [3rd] dose for moderately and severely immunocompromised persons): - Should be given to persons 18 years of age and older (flue of heterologous- mix and match – booster doses is allowed) - May be given to persons 16 and 17 years of age based on individual benefits and risks		Abooste dose, at least Z months (8 weeks) after the primary Janess ningle dost of heterologous (mix and match) booster doses is allowed. - Should be given to all persons who 18 years of a ge an older (ble of heterologous mix and match) booster doses is allowed. - A moderately or severely immunocompromised person who receives a primary Janesen COVID-19 Vaccine should not receive men than 1 booster dost old 2 doses).
		nsiderations-covid19-vax-immunocopromised		
Interval between primary and booster doses	n/a	At least 6 calendar months after completing the primary series or additional primary dose (for moderately or severely immunocompromised)	At least 6 calendar months after receiving the primary series or additional primary dose (for moderately or severely immunocompromised)	At least 2 months (8 weeks) after receiving the primary dose

12/13/2021 CS321571-W

CDC Vaccine Storage and Handling Toolkit



View or Print Toolkit

The Vaccine Storage and Handling Toolkit is a comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.

Vaccine Storage and Handling Resources

Access additional <u>resources</u> including web-based trainings, videos, checklists, and references related to vaccine storage and handling.

These example vaccine labels can be used to organize vaccines within the storage unit. Referenced in the storage and handling toolkit.

- 2020-2021 Influenza Season Vaccine Label Examples 🔼 [4 pages] (Sept 2020)
- Vaccine Labels Examples 🚨 [20 pages] (Jan 2021)



<u>Interim Considerations: Preparing for the Potential</u> <u>Management of Anaphylaxis at COVID-19 Vaccination Sites</u>

- Emergency equipment that should be immediately available
- Routine observation periods following COVID-19 vaccination
- Early recognition of anaphylaxis
- Management of anaphylaxis at a COVID-19 vaccination location
- Considerations for anaphylaxis management in special populations
- Patient counseling
- Reporting anaphylaxis

Locations administering COVID-19 vaccines should adhere to CDC guidance, including screening recipients for contraindications and precautions, having necessary supplies and staff members available to manage anaphylaxis, implementing recommended post vaccination observation periods, and immediately treating suspected anaphylaxis with intramuscular epinephrine injection.

CDC v-safe system

- Give patients a v-safe information sheet at the time of vaccination
- Suggested healthcare provider script: CDC has created a way for you to report how you feel after COVID-19 vaccination through a smartphone-based tool that uses text messaging and web surveys to check in with you. Here (or in your packet) is a v-safe information sheet with more details and simple instructions to sign up.
- Parents and guardians can now enroll adolescents (ages 5 and older) in the v-safe after vaccination health checkersM and complete health check-ins on their behalf after COVID-19 vaccination.
- Poster and website translated into multiple languages



What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through v-safe, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And v-safe will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's *v-safe* makes a difference — it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in *v-safe* using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from *v-safe* around 2pm local time. To opt out, simply text "STOP" when *v-safe* sends you a text message. You can also start *v-safe* again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, *v-safe* will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions *v-safe* asks should take less than 5 minutes to answer. If you need a second dose of vaccine, *v-safe* will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in *v-safe* is protected so that it stays confidential and private.*

To the extent v-safe uses existing information systems managed by CDC, EDA, and other federal agencies, the systems employ sirt dis ecuty messure appropriate for the data is level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health insurance Portability and Accountability. Act of 1966 (HIPAA); the Federal Information Security Management Act, and the Federal Information Security Management Act, and the Federal Information Security Management Act, and the



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at

OR

Aim your smartphone's camera at this code



VAERS Reporting and Safety Info - <u>vaers.hhs.gov</u>

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event.



ADHS Vaccine Reference Sheets

Comirnaty/Pfizer Gray Cap (Age 12+)

• Comirnaty/Pfizer Vaccine Reference Sheet

Comirnaty/Pfizer Purple Cap (Age 12+)

- Comirnaty/Pfizer Vaccine Reference Sheet
- ADHS Dry Ice Handling/Recharge Flyer

Pfizer Orange Cap (Age 5-11)

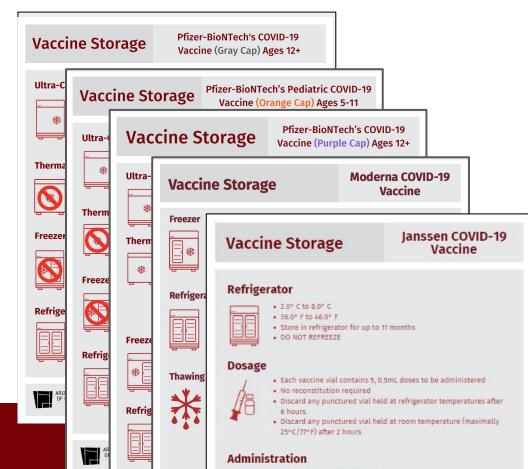
<u>PEDIATRIC Pfizer Vaccine Reference Sheet</u>

Moderna (Age 18+)

- Moderna Vaccine Reference Sheet
 - Wastage Reporting Table

Janssen (Age 18+)

- Janssen Vaccine Reference Sheet
- What Patients and Providers Need to Know About the Janssen Vaccine



EUA Fact Sheets

Routine vaccines are given with a Vaccine Information Statement (VIS) COVID-19 vaccines under the Emergency Use Authorization (EUA) will be given with an EUA Factsheet.

- Comirnaty/Pfizer Fact Sheet
- Comirnaty and Pfizer EUA fact sheet translated in other languages
 - Includes Pediatric Pfizer (Age 5-11) fact sheets
- Moderna Fact sheet
- Moderna EUA fact sheet translated in other languages
- <u>Janssen Fact Sheet</u>
- Janssen EUA fact sheet translated in other languages

COVID-19 Vaccine Presentations Job Aid



*Pfizer-BioNTech (Ages 12+) - Purple Cap 1170 is no longer available to order in ASIIS.

Pfizer-BioNTech (Ages 12+, NO diluent) - Gray Cap is now available to order in ASIIS.

300-dose minimum order

- 6 dose multi-dose vials (0.3mL)
- Shipped in a single use thermal shipping container,
 DO NOT return
- Controlant data logger included in shipment must be returned

COVID-19 Vaccine Presentations Available to Order in ASIIS



Pfizer-BioNTech (Ages 12+, No Diluent) - Gray Cap

- 6-dose multi-dose vial (0.3 mL)
- Shipped in a single use thermal shipping container, DO NOT return
- Controlant data logger included in shipment must be returned
- NDC 59267-1025-04



Pediatric Pfizer-BioNTech (Ages 5-11) - Orange Cap

100-dose minimum order

- 10-dose multi-dose vial (0.2 mL)
- · Shipped in a single use thermal shipping container, DO NOT return
- · Controlant data logger included in shipment must be returned
- NDC 59267-1055-04



Moderna (Ages 18+)

100-Dose Minimum Order

- 10-dose multi-dose vial (range: 10-11 doses) (0.5 mL)
- NDC 80777-0273-99



Janssen (Ages 18+)

100-Dose Minimum Order

- 5-dose multi-dose vial (0.5 mL)
- NDC 59676-0580-15

FDA gives Moderna COVID-19 vaccine full approval for use in ages 18 and older

- The Food and Drug Administration (FDA) has given full approval to the Moderna COVID-19 vaccine for use in those ages 18 and older.
- Moderna joins the Pfizer-BioNTech vaccine, which the FDA gave full approval to last August for
 use in ages 16 and older. Ages 5 to 15 are eligible for the Pfizer COVID-19 vaccine under an
 FDA emergency use authorization.

Moderna Label Update

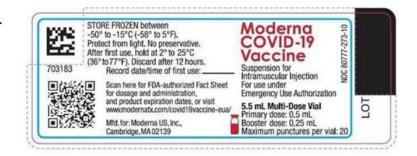
FDA recently approved updates to both label and the EUA fact sheet for the Moderna COVID-19 vaccine. Distribution of the Moderna vials with the updated labels (see new label above) began during the week of January 13, 2021.

What has changed on the label of the Moderna COVID-19 vaccine:

- The label has been updated to indicate a volume of 5.5mL.
- Doses for primary series and booster shots are now listed on the label.
- Important reminder not to exceed a maximum of 20 punctures per vial

What remains the same for the Moderna COVID-19 vaccine:

- Formulation
- NDC
- Physical vial size
- Number of reportable doses
- Dose volumes (See Below)
- Reporting requirements
 - Wastage should continue to be reported based on 10 doses per vial.
- Proper dosage of Moderna COVID-19 Vaccine
 - Primary series doses 1 and 2 dosage = 0.5 mL
 - Additional primary dose (3rd) dosage for immunocompromised persons = 0.5 mL
 - Booster dosage = 0.25 mL
- Each vial can ONLY be punctured up to 20 times.
 - Once the vial has reached the 20-puncture limit, the vial should be discarded **even if there is** vaccine remaining in the vial.



For more information, please refer to the <u>EUA fact sheet</u> or <u>Administration Overview for Moderna COVID-19 Vaccine | CDC.</u>

Moderna Booster Reporting of Administered and Wasted Doses

- Quick rule of thumb: As long as the vial has been punctured 10 or 14 times and 10 or 14 doses were administered (regardless if they were full primary series doses or half booster doses) there will be no reported wastage.
- Example from the 14 dose vial table: 5 full doses (primary series) were administered and 5 half doses (booster doses) were administered before the 12 hour limit was reached. 4 doses should now be reported as wastage.

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doses Half Doses	0	1	2	3	4	5	6		7	8	9		10					
0	10	9	8	7	6	5	4	1	3	2	1		0					
1	9	8	7	6	5	4	3	:	2	1	0)						
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3	7	6	5	4	3	2	1		0									
4	6	5	4	3	2	1	0)										
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11							-Be .											
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13		_	1		1													
15				oses					,		,	8	9	10	111	12	15	14
			Half Doses															
14			Half Doses	14		12	11	10	9	8	7	6	5	4	3	2	1	0
14 15			Half Doses		12	12 11 10	11 10 9											
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14 15 16 17			Half Doses 0 1 2 3	14 13 12 11 10	12 11 10 9	11 10 9 8	10 9 8 7	10 9 8 7 6	9 8 7 6 5	8 7 6 5	7 6 5 4	6 5 4 3	5 4 3 2	4 3 2	3 2 1	2	1	
14 15 16			Half Doses 0 1 2 3 4	14 13 12 11 10 9	12 11 10 9 8	11 10 9 8 7	10 9 8 7 6	10 9 8 7 6 5	9 8 7 6 5	8 7 6 5 4 3	7 6 5 4 3	6 5 4 3 2	5 4 3 2	4 3 2	3 2 1	2	1	
14 15 16 17			Half Doses 0 1 2 3	14 13 12 11 10	12 11 10 9	11 10 9 8	10 9 8 7	10 9 8 7 6	9 8 7 6 5	8 7 6 5	7 6 5 4	6 5 4 3	5 4 3 2	4 3 2	3 2 1	2	1	
14 15 16 17 18 19			Half Doses 0 1 2 3 4 5 6 7	14 13 12 11 10 9 8 7 6	12 11 10 9 8 7 6 5	11 10 9 8 7 6 5	10 9 8 7 6 5 4	10 9 8 7 6 5 4 3	9 8 7 6 5 4 3 2	8 7 6 5 4 3	7 6 5 4 3 2	6 5 4 3 2	5 4 3 2	4 3 2	3 2 1	2	1	
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Moderna Puncture Tracking Log

- Keep track of how many times vials have been punctured
- Vials can only be punctured maximum of 20 times
- Mark half-doses vs full doses
- Can track 2 vials per log

Moderna Puncture Tracking Log

Vial Lo	t #:	2				
Start T	ime:	End Time:				
Dose	Full (0.5 mL)	Half (0.25 mL)				
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
To delicate						

Vial Lo Start T		End Time:				
	Full (0.5 mL)	Half (0.25 mL)				
	- C. (0.0 III.E)	(0.20 III.2)				
1		닏				
2						
3						
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20						

Reminders

- Moderna booster doses are 0.25mL (half the dose size of a primary series dose)
- . Moderna vials can only be punctured a maximum of 20 times
- . Providers are responsible to keep track of the number of punctures for each vial
- · Punctured Moderna vials can be used to administer both primary and booster doses
- · Punctured Moderna vials must be used within 12 hours

602-364-3899 ArizonaVFC@azdhs.gov azdhs.gov/covid19/vaccines

Pediatric Pfizer (Age 5-11) COVID-19 Vaccine Authorized

- The Pfizer COVID-19 Vaccine is over 90% effective at preventing COVID-19 in children ages 5 through 11 years.
- COVID-19 vaccines have undergone—and continue to undergo—the most intensive safety monitoring in U.S. history. In clinical trials of about 3,000 children, serious side effects were rare and self-limiting.
- After getting a COVID-19 vaccine, children may have some side effects similar to those seen in adults and with other vaccines which is normal.
- This recommendation was made based on in-depth review of available safety, immunogenicity, and efficacy data.
- Pediatric COVID-19 vaccines will be available at no cost.

You can only puncture the diluent once

Orders of Pfizer age 5-11 vaccine include ancillary kits that contain 10mL diluent vials. While these vials appear to contain sufficient diluent for multiple vials, they must only be used once.

- Diluent vials are a one-time-use item and should be discarded with the remaining content after each use.
- For each vial of vaccine, extract 1.3mL of diluent from a single-use vial to reconstitute 1.3mL of vaccine
- Do not be tempted to puncture diluent vials more than once.

Pfizer pediatric doses (5-11) should NOT be reported as adult doses

Reminder:

The CPT and CVX codes for the Pfizer age 5-11 vaccine and the Pfizer age 12+ vaccine are different.

Please ensure that your EHR has been updated to document the vaccines correctly.

For information on Arizona HL7 Specific Rules for Version 2.5.1, click <u>here</u>.

For information on List of Vaccine Names, Best ASIIS Selection and CPT/CVX Codes, click <u>here</u>.

List of Vaccine Names, Best ASIIS Selection and CPT/CVX Codes

MSH.11



This list matches the vaccine name or codes in Arizona State Immunization Information System (ASIIS) with the brand name or other common names of the vaccines you use most often.

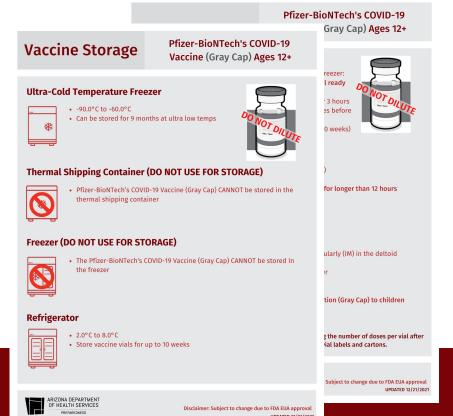
Vaccine trade na	me or common name	Fund	Best ASIIS Selection	Age (Range)	Dose	Route	Manufacturer/ NDC Number	CPT Code	CV
COVID-19 Vaccines									
COMIRNATY		PAN	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose	16+ years 12+ years EUA	0.3 ml	IM	Pfizer, INC – PFR NDC: 59267-1000-02 (195pack-6dose vials) (1170 doses)	91300	208
Pfizer COVID-19 Vacc	ine	PAN	COVID-19, mRNA, LNP-S, PF, 10 mcg/0.2 mL dose, tris-sucrose	5≺12 years EUA	0.2 ml	IM	Pfizer, INC – PFR NDC: 59267-1055-04 (10pack-10dose vials) (100 doses)	91307	218
Moderna COVID-19	9 Vaccine	PAN	COVID-19, mRNA, LNP-S, PF,	18+ years	0.5 ml	IM	Moderna – MOD NDC: 80777-0273-99 (10pack-10dose vials) (100 doses)	91301	207
Janssen COVID								91303	212
AstraZeneca COVID-			Arizona HL7 Specif					91302	210
Novavax COVID-19			ns and rules supersede mmunization Program						211
	MSH.1	– Field Se	parator will be the pipe	identified as	(ASCII 24	1)			+
Sinopharm (BIBP) Ci	MSH.2	– Encodin	g Characters will be ^~	& identified as	(ASCII 9	4, ASCII :	126, ASCII 92, ASCII 38)		510
Coronavac (Sinovac		respective	ely.						511
SARS-COV-2 (COVID	MSH.3	- Sending	Application is required	1					213
	MSH.4	 Sending ASIIS Syst 	Facility is required and em.	d shall be the IR	MS ID as	signed a	nd provided by the		
	MSH.5	– Receivir	ng Application is requir	ed and shall alv	ays be A	SIIS.			
	MSH.6	– Receivir	ng Facility is required a	nd shall always	be ASIIS				
	MSH.7		me of Message is requi						
	MSH.9		e Type is required and son Messages.	shall be VXU^V	04^VXU_	_ V04 for	Unsolicited		
	MSH.10		e Control ID is required acility with a maximum			each me	essage attempt from a		

Processing ID is required and because the ASIIS system has separate points for



Pediatric Pfizer Gray Cap (12+) Job Aid

- *NEW* Can be stored in ULT freezers for up to 12 months
- Can be refrigerated for up to 10 weeks
- DO NOT use thermal shipping container or standard freezer for storage
- 6-dose vial
- DO NOT dilute prior to use
- DO NOT keep vaccine at room temperature for longer than 12 hours
- Discard vial 12 hours after first puncture



<u>Pediatric Pfizer Orange Cap (Ages 5-11) Manufacturing Date vs Expiration Date</u>

- Date printed on vial and tray is manufacturing date only
- Base expiration date on storage method and manufacturing date. For example:
 - o If the manufacturer date is 8/2021 and the doses are stored in an ultra-low-temp freezer, the doses would expire April 30, 2022.
 - If the doses are put in the refrigerator November 2, 2021, they would expire
 weeks from November 2 on January 11, 2022.
- Use <u>Pfizer Age 5-11 EUA Fact Sheet</u> (Page 3)
- Use <u>Pfizer website</u>

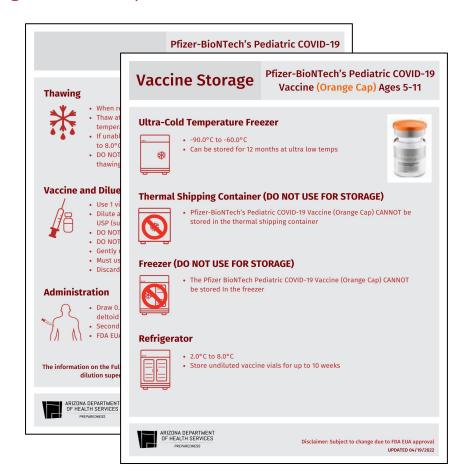
Pediatric Pfizer Orange Cap (Ages 5-11) Shippers

- Shipper CANNOT be used for temp storage
- Can only be stored in ULT freezers and refrigerators
- Shipper does not need to be returned
- Controlant data logger does need to be returned



Pediatric Pfizer Orange Cap (Ages 5-11) Job Aid

- *NEW* Can be stored in ULT freezers for up to 12 months
- Can be refrigerated for up to 10 weeks
- DO NOT use thermal shipping container or standard freezer for storage
- 10-dose vial
- Draw 0.2mL of diluted vaccine
- Discard 12 hours after dilution



Pfizer Purple Cap (Age 12+) Job Aid

Vaccine Storage

Pfizer-BioNTech's COVID-19 Vaccine (Purple Cap) Ages 12+

Ultra-Cold Temperature Freezer



- -90.0°C to -60.0°C
- · Can be stored for 9 months at ultra low temps



Thermal Shipping Container with Dry Ice Pellets



- Will maintain -90.0°C to -60.0°C for up to 30 days upon re-icing
- · Up to 6 recharges (re-icings) are authorized
- 1st recharge (re-icing) within 24 hours of receipt and upon opening the thermal shipper
- Dry ice recharges will NOT be provided for any configurations
- Re-icings required every 5 days after the 1st re-icing to maintain temperature
- May only be opened up to 2 times per day (≤ 3 minutes per opening)

Freezer



- -25.0°C to -15.0°C
- · Store for up to 2 weeks
- May be returned one time to the recommended storage condition of -90.0°C to -60.0°C

Refrigerator



2.0°C to 8.0°C

Thav



Thawing



- · When removing from ultra-cold temperature:
- Thaw at 2.0°C to 8.0°C for 3 hours OR Thaw at room temperature for 30 minutes
- If unable to dilute, store thawed undiluted vials at 2.0°C to 8.0°C (up to 1 month)
- DO NOT open vial trays or remove vials until ready for thawing or use



Vaccine and Diluent



- · Use 1 vial for every 6 recipients (6-dose vial)
- Dilute a single thawed vial with 1.8mL of 0.9% Sodium Chloride Injection, USP (supplied with ancillary kit)
- . DO NOT USE ANY OTHER DILUENT
- · DO NOT shake vial upon dilution
- · Gently mix by turning vial over and back 10 times
- · Must use diluted vaccine within 6 hours
- · Discard any unused, diluted vaccine after 6 hours

Administration



- Draw 0.3mL of diluted vaccine and inject intramuscularly (IM) in the deltoid muscle
- · Second dose due a minimum of 21 days later
- Full FDA Approval for ages 16+
- FDA EUA approval still for ages 12-15 years
- Pregnant/lactating women can choose to be vaccinated talk with your healthcare provider
- DO NOT administer the Pfizer adult formulation (purple cap) to children

COVID-19 Vaccine Transfer Matchmaker Tool

- Share vaccine with other active COVID-19 providers
- Request vaccine from nearby locations if active providers need vaccine
- You can transfer needles as well
- Only serves as connection between providers
- All transfers must still have prior approval in ASIIS, must follow all transfer steps
- Matchmaker Tool Job Aid
 - Transfer steps
 - Helpful resources linked

COVID-19 Vaccine Transfer Matchmaker





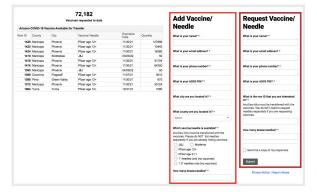
Do you have more vaccines than you can use?

List them on the <u>Arizona COVID-19 Vaccine Transfer</u>
<u>Matchmaker Website</u> using the "Add Vaccine/Needle"
form on the website.



Do you need to place a vaccine order?

First, check the <u>Arizona COVID-19 Vaccine Transfer</u> <u>Matchmaker Website</u> for vaccine available at a location near you, and submit a "Request Vaccine/Needle" form on the website. The table on the left shows vaccines that are available for providers to request.



ACIP Recommends 3rd Dose for Immunocompromised

- People who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise
- Additional dose should optimally be the same mRNA vaccine as the primary series
- If that brand is not available, the other brand of mRNA COVID-19 vaccine can be used
- Additional dose should be administered 28+ days after primary mRNA COVID-19 vaccine series
- Does not apply to individuals who received Janssen COVID-19 as a primary series
- Web page for consumers
- Web page for healthcare providers
- Please diligently screen patients and check patients' vaccination history in ASIIS
- If you discover 3rd dose was inadvertently administered:
 - Review <u>CDC COVID-19 Administration Errors and Deviations</u>

<u>ADHS Consent Form Template</u>

- No Federal requirement for informed consent relating to immunization
- Available for providers who do not have own consent form
- Use with <u>CDC Pre-Vaccination checklist</u>
- Spanish ADHS consent form
- Spanish CDC Pre-Vaccination Checklist

for COVID-19 Vaccine	klist es		DC	
for vaccine recipients:	Patient Name			
he following questions will help us determine if there is ny reason you should not get the COVID-19 vaccine today. you answer "yes" to any question, it does not necessarily n	Age			
hould not be vaccinated. It just means additional questions n	nay be asked.			Don't
	nay be asked.	Yes	No	Don't
hould not be vaccinated. It just means additional questions n	nay be asked.	Yes	No	
hould not be vaccinated. It just means additional questions in a question is not clear, please ask your healthcare provider to	nay be asked.	Yes	No	

ADHS COVID-19 Vaccine Consent Form Use this form in conjunction with the CDC Pre-Vaccination Checklist for COVID-19 Vaccines. (Staff only) Appointment ID: Patient Information Middle Name (optional) Last Name First Name Mother's Maiden Name (Optional) Date of Birth (MM/DD/YYYY) Gender Address State Apartment Number () No address available Phone Number Insurance Information Do you have insurance? Yes No Email Address Plan Name Plan Group ID # Plan Individual ID # Name of Person Covered By Plan Plan Responsible Person Name Private Insurance Address and Phone Number (If Available) CONSENT AND ASSIGNMENT OF BENEFITS; I have had a copy of the Emergency Use Authorization for the COVID-19 vaccine made available to me. I have had a chance to ask questions and I believe I understand the benefits and risks of the COVID-19 vaccines requested. I ask that the vaccines be administered to me or the person for whom I am authorized to make this request. Legify that Lam: (1) the patient and at least 18 years of age: (2) the legal guardian of the patient and the patient's age makes him/her eligible to receive the vaccine bases on the current emergency use authorization; or (3) a person authorized to consent on behalf of the patient where the patient is unable to consent for themselves any insurance or other third-party benefits available for the administration fee of the COVID-19 vaccine provided to me. I agree to forward to rendered to me immediately upon receipt Lagree to allow the health care provider to release information to the Arizona State Immunization Information System (ASIIS) to record that I for fire the person for who am authorized to consent) have received this COVID-19 vaccine. This information will help keep track of the manufacturer and doses of the vaccine Patient Printed Name Patient Signature Date Signed Parent/Guardian/Authorized Person Printed Name Date Signed Authorized Person's Signature Vaccine Administration Information for Immunizer Use Only NDC # Administration Date Manufacturer LEFT ARM RIGHT ARM Lot Number **Expiration Date** Route Site Administering Immunizer Name and Title Administering Immunizer Signature Is this the patient's first, second, or third dose? First Second Third

ADHS Does Not Provide Exemption Forms for Adults for the COVID-19 Vaccine

- Individual facilities and employers may choose to set their own immunization requirements for adults
- If an employer is requiring a COVID-19 Vaccine for their employees, and the employee is refusing vaccination, direct that patient to their Human Resources department
- Adults who have questions on immunization exemptions, for any vaccine, should contact the facility or employer who has set the requirement

Standing Order Links

Link to Moderna

Moderna COVID-19 Vaccine Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older



Vaccine	Dosage (amount)/ Route
Moderna-Primary Series	0.5 mL/IM injection
Moderna-Booster Dose	0.25mL/IM injection
P	unceined/covid 10/clinical considerations/covid 10 vaccines

 To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

 Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Assess persons 18 years of age and older for vaccination with

of least 28 days.

Moderna COVID-19 Vaccine based on the following criteria: Primary-series vaccination

- o If the recipient has never received a COVID-19 vaccine, administer 1 dose of Moderna COVID-19 Vaccine.
- o If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at an interval
- o If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after
- If 2 doses of an mRNA vaccine or a single dose of lanssen. COVID-19 Vaccine has been administered, the person is considered fully vaccinated 2 weeks after completing the primary vaccination series.
- Persons with a history of myocarditis or pericarditis:
- o If history is prior to COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
- If myocarditis or pericarditis occurs after a dose of an

us.html#considerations-pfizer-biontech-moderna

- Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.
- Additional primary dose for persons who are moderately or severely immune compromised
- For a person aged 18 years and older who received a Moderna primary mRNA vaccine series: Administer an additional primary dose of Moderna vaccine at least 28 days after an intial 2-dose Moderna primary series. If the vaccine product cannot be determined or is no longer available. administer either mRNA COVID-19 product.
- Persons who have received HCT or CAR-T-cell therapy
- Revaccinate persons who received doses of COVID-19 vaccine prior to receiving HCT or CAR-t-cell therapy with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy
- Administer a booster dose, at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., the 2nd dose or additional primary series dose for moderately or severely immunocompromised persons) to persons 18 years of age and older
- Persons previously vaccinated with Janssen COVID-19 Vaccine: Administer a booster dose at least 2 months after the Janssen COVID-19 Vaccine primary series.
- Use of heterologous booster doses is allowed. Any FDAapproved or FDA-authorized COVID-19 vaccine product can he administered
- For additional information, see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States https://www.

Link to Pfizer





Dosage (amount)/ Route

1.8 mL of 0.9% sodium chloride (normal saline, Formulation: 12 years of age 0.3 mL/IM injection preservative-free) diluent and older (purple cap) To reduce morbidity and mortality from coronavirus disease us.html#considerations-pfizer-biontech-moderna

2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

 Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Assess persons 12 years of age and older for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria:

- Primary-series vaccination
- If the recipient has never received a COVID-19 vaccine. administer 1 dose of Pfizer-BioNTech COVID-19 vaccine
- If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days.
- If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after
- If 2 doses of an mRNA vaccine or a single dose of Janssen COVID-19 Vaccine has been administered, the person is
- considered fully vaccinated 2 weeks after completing the primary vaccination series.
- Persons with a history of myocarditis or pericarditis:
- If history is prior to COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
- If myncarditis or pericarditis occurs after a dose of an

team. Considerations can be found at https://www.cdc.gov/ vaccines/covid-19/clinical-considerations/covid-19-vaccines-

- Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.
- Additional primary dose for persons who are moderately or severely immune compromised
- o For a person aged 12 years and older who received a Pfizer-BioNTech primary mRNA vaccine series: Administer an additional primary dose of Pfizer-BioNTech vaccine at least 28 days after an intial 2-dose Pfizer-BioNTech primary series. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 product.
- Persons who have received HCT or CAR-T-cell therapy
- Revaccinate persons who received doses of COVID-19 vaccine prior to receiving HCT or CAR-T-cell therapy with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy
- Booster doses
- A booster dose, at least 6 calendar months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose or the additional [3rd] dose for moderately or severely immunocompromised persons)
- Should be administered to persons 18 years of age and older (Use of heterologous - mix and match - booster doses is allowed)
- May be administered to persons 16 and 17 years of age based on their individual benefits and risks
- Additional Clinical Considerations
- For persons who received a COVID-19 vaccine:
- Outside of the United States

Link to lanssen





Janssen COVID-19 Vaccine (Johnson & Johnson) 0.5 mL/IM injection

 To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

 Where authorized under state law standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction

Assess persons 18 years of age and older for vaccination with Jansson COVID-19 Vaccine based on the following criteria-

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of Janssen COVID-19 vaccine.
- If the recipient has received 1 dose of a Janssen COVID-19 Vaccine no additional primary-series doses are needed. A booster dose is recommended 2 months (8 weeks) after the primary Janssen dose; any FDA-authorized or approved
- COVID-19 vaccine may be given. If 2 doses of an mRNA vaccine or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated 2 weeks after completing the primary vaccination series.
- In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine, (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days after receipt of mRNA COVID-19 vaccine dose. However vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic

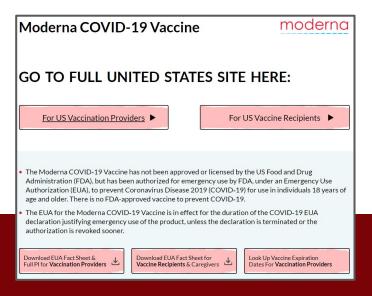
- Thrombocytopenia syndrome (TTS) and thrombocytopenia: Inform women aged 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group after Janssen COVID-19 vaccination and about the
- availability of other authorized vaccines (i.e., mRNA vaccines). A second dose of Janssen COMD-19 vaccine is not recommended for neonle who had TTS after their first dose These people may receive a dose of mRNA COVID-19 vaccine as a booster dose at least 2 months (8 weeks) after their dose of Janssen vaccine and after their clinical condition has stabilized.[†]
- A consultation with the patient's clinical team, including hematologists or other specialists, should be considered
- Offer another FDA-authorized or approved vaccine (i.e., mRNA vaccine) to unvaccinated persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized or approved COVID-19 vaccine.

NOTE: Persons at risk or with a history of other thrombosis not associated with thrombocytopenia can receive an FDAauthorized or approved vaccine

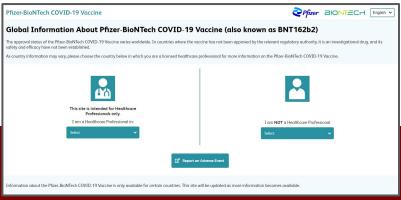
- People with a history of Guillain-Barré Syndrome (GBS):
- Can receive any FDA-authorized or approved COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, discuss with these patients the availability of mRNA COVID-19 vaccines that offer protection against COVID-19
- Persons who have received HCT or CAR-T-cell therapy Revaccinate persons who received doses of COVID-19 vaccine
- prior to receiving HCT or CAR-T-cell therapy with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- Administer a honster dose at least 2 months (8 weeks) after completion of the Janssen COVID-19 Vaccine primary dose to:

Vaccine Manufacturer COVID-19 Websites

- Comirnaty/Pfizer COVID-19 Website
- Moderna COVID-19 Website
- Janssen COVID-19 Website

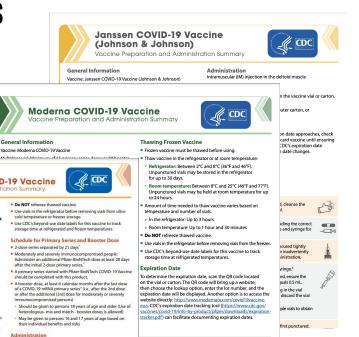






CDC COVID-19 Vaccine Resources

- CDC Pfizer (Comirnaty) Resource Page
- CDC Moderna Resource Page
- CDC Janssen Resource Page



Unpunctured vials: Check the expiration date

Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.

With the vial upright, gently swirl the vaccine.

Do NOT shake, If the vial is shaken, contact the

manufacturer. Note: Gently swirl the vaccine before

3

Never use expired vaccine.

withdrawing subsequent doses.

Intramuscular (IM) injection in the deltoid muscle

With the vaccine at room temperature, gently invert

white to off-white in color and may contain opaque

Using a new, sterile alcohol prep pad for each vial,

withdraw 1.8 mL of 0.9% sodium chloride (normal

Discard diluent vial and any remaining diluent every time. Do NOT use bacteriostatic normal saline or

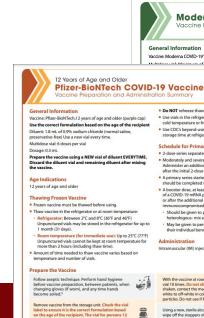
wipe off the stoppers of the diluent and vaccine

saline, preservative-free) into a mixing syringe.

vials. Using a 21-gauge (or narrower) needle.

vial 10 times. Do not shake the vial. If the vial is shaken, contact the manufacturer. The vaccine is

particles. Do not use if liquid is discolored.



years of age and older has a purple cap and purple

border on the label. Allow vaccine to come to room

up to 2 hours before mixing.

Refore mixing check the · emiration date on the vaccine and diluen any beyond-use dates/times NEVER use expired vaccine or diluent. NEVER use vaccine after the beyond-use date or times.

perature. Vials can be held at room temperature for

COVID-19 Vaccine Expiration Dates

Pfizer Purple Cap (Age 12+)

- Find on vial and tray
- On tray under lot number that's highlighted in yellow
- On vial circled in red below





Pfizer Orange Cap (Age 5-11)

- Date printed on vial and tray is manufacturing date only
- Use <u>Pfizer Age 5-11 EUA Fact Sheet</u> (Page 3)
- Use <u>Pfizer website</u>

Base expiration date on storage method and manufacturing date. For example:

- If the manufacturer date is 8/2021 and the doses are stored in an ultra-low-temp freezer, the doses would expire April 30, 2022.
- If the doses are put in the refrigerator November 2, 2021, they would expire 10 weeks from November 2 on January 11, 2022.

Pfizer Gray Cap (12+)

- Date printed on vial and tray is manufacturing date only
- Use <u>Pfizer Gray Cap (Ages 12+) EUA</u> <u>Fact Sheet</u> (Page 5)
- Use <u>Pfizer website</u>

Base expiration date on storage method and manufacturing date. For example:

- If the manufacturer date is 8/2021 and the doses are stored in an ultra-low-temp freezer, the doses would expire April 30, 2022.
- If the doses are put in the refrigerator November 2, 2021, they would expire 10 weeks from November 2 on January 11, 2022.

Moderna

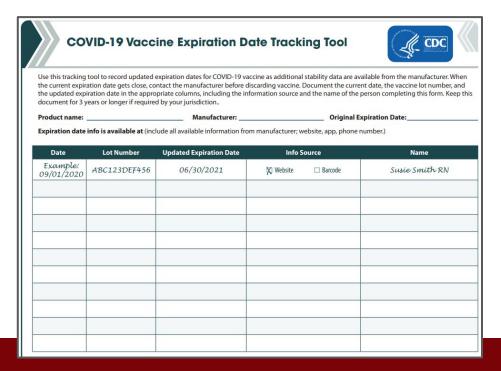
- Use QR code
- Enter lot number on <u>expiration</u> date checker website

Janssen

- Use OR code
- Enter lot number on <u>expiration date</u> <u>checker website</u>
- Can be used until 11:59 EST on expiry date

CDC Expiration Date Tracking Tool

- Comirnaty/Pfizer Purple Cap (Age 12+) doses can be stored frozen (-20° C) for up to two weeks and/or refrigerated for up to one month
- Pfizer Orange Cap (Age 5-11) doses can be refrigerated for up to 10 weeks
- Moderna doses can be refrigerated for up to 30 days
- Janssen doses can be refrigerated for up to 11 months
- Providers should check the latest expiry information on the manufacturer's website before doses are removed from the unit



COVID-19 Vaccine and Beyond-use Dates (BUDs)

- CDC has developed tracking labels refrigerators and freezers to help monitor and document cold storage dates
- Assist with documenting transportation time and temperature
- Available for both Moderna and Pfizer/Comirnaty vaccines
- Moderna COVID-19 Vaccine: Beyond Use Date/Time (BUD) Tracking Label for Vaccine During Refrigerator Storage (cdc.gov)
- <u>Pfizer-BioNTech COVID-19 Beyond Use Date/Time (BUD) Tracking Labels for Vaccine During Freezer or Refrigerator Storage (cdc.gov)</u>

Returning Thermal Shipping Containers (Once Empty)

Pfizer (Gray Cap)

- Shippers DO NOT need to be returned
- Only controlant data logger needs to be returned

Comirnaty/Pfizer (Purple Cap ONLY)

- Turn off the temperature monitoring device
- Return the shipping containers and temperature monitors
- Return label included with the box
- <u>Instructions</u> on returning Comirnaty/Pfizer thermal shipper

Pfizer (Orange Cap)

- Shippers **DO NOT** need to be returned
- Only controlant data logger needs to be returned

Moderna

Return using the return label located on the inside of the box

Janssen shippers do not need to be returned

Excess ancillary kit supplies do not need to be returned, can be used for other purposes in facility

Vaccine Process

Vaccines are widely available

- Providers enter COVID-19 vaccine order in ASIIS
- AIPO will approve the order
- Order goes to CDC to Distributor/Manufacturer
- Order is shipped (will show in ASIIS)
- Provider receives shipment of ancillary kit and vaccine (may not be same day)
- Provider logs into ASIIS to mark doses as "received"
- Provider administers vaccine
- Provider reports the administered vaccine to ASIIS through their EHR, State VMS POD application, directly in ASIIS or using Mass Immunization Module in ASIIS
- The dose is subtracted from the ASIIS inventory

ASIIS Information

<u>Placing Orders in ASIIS</u>

- Providers who have an approved onboarding submission are able to order vaccines
- AIPO Train courses
 - How to Place an Order in ASIIS
 - Vaccine Inventory Management information on ordering and inventory reconciliation
 - Sign up for Dose Accountability Webinar
 - Recordings available any time within AIPO
 Train course
 - Included in Pandemic Provider course bundle
- Use <u>COVID-19 Vaccine Presentations Job Aid</u> to help make ordering decisions



COVID-19 Vaccine Presentations Available to Order in ASIIS



Pfizer-BioNTech (Ages 12+, No Diluent) - Gray Cap

- · 6-dose multi-dose vial (0.3 mL)
- · Shipped in a single use thermal shipping container, DO NOT return
- Controlant data logger included in shipment must be returned
- NDC 59267-1025-04



Pediatric Pfizer-BioNTech (Ages 5-11) - Orange Cap

100-dose minimum order

- 10-dose multi-dose vial (0.2 mL)
- · Shipped in a single use thermal shipping container, DO NOT return
- · Controlant data logger included in shipment must be returned
- NDC 59267-1055-04



Moderna (Ages 18+)

100-Dose Minimum Order

- 10-dose multi-dose vial
 (0.5)
- (range: 10-11 doses) (0.5 mL)
 NDC 80777-0273-99



Janssen (Ages 18+)

100-Dose Minimum Order

- · 5-dose multi-dose vial (0.5 mL)
- NDC 59676-0580-15

Vaccine Transfer Process

- Both the sending and receiving providers will email data logger reports to <u>ArizonaVFC@azdhs.gov</u>
- Transfers must be approved in ASIIS prior to moving the doses
 - Enter the transfer in ASIIS prior to moving the doses
 - Information you will need for ASIIS
 - 1. The organization and facility sending the doses
 - 2. The organization and facility receiving the doses
 - 3. The quantity
 - 4. The lot number
 - When the doses arrive, mark them <u>"received" in ASIIS</u>. Do not administer doses before "receiving" them in the ASIIS inventory
- Only onboarded, active COVID-19 vaccine providers may receive COVID-19 vaccines
- Follow the <u>USP transfer guidelines</u> when packing the doses for transfer
 - Once frozen doses have been thawed they cannot go back into a freezer
- Wherever the vaccines are, data loggers must be with them to monitor the temperatures
- The ancillary kit must also be transferred with the doses

Vaccine Wastage

- If vaccine expires before you can use it:
 - Complete the <u>AIPO wastage form</u> (Must be signed by the enrolling provider)
 - Please compile all wasted doses for the week onto one form and submit this form once a week, not daily.
 - 2. Email the completed form to arizonavfc@azdhs.gov
 - 3. Dispose of the vaccine
- Expired/wasted COVID-19 doses should be disposed of in a sharps container or per the hazardous waste policy in your office
- Tear off the vial labels or mark the identifying information (lot number, NDC number, etc) with a black marker prior to disposing
- Expired/wasted COVID-19 vaccines DO NOT go back to McKesson or Pfizer at this time
- How to Account for Wasted/Expired Doses Job Aid

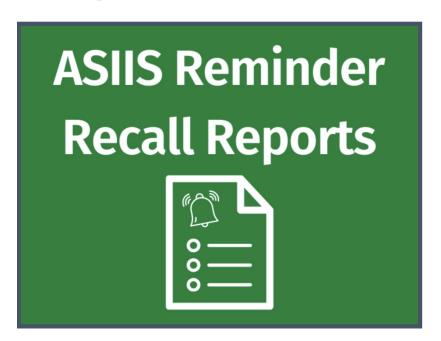
<u>Correcting Negative Doses in ASIIS</u>

Reconciling ASIIS inventory

- Giving more doses than what is in the ASIIS inventory will make the inventory
- negative, which will mean you cannot submit inventory reconciliation
- Only if extracting extra doses from a vial
 - Ex. Extracting 15 doses from Moderna 14-dose vial
- AIPO Train module: Correcting Negative COVID-19 Doses in ASIIS

How to Run Reminder/Recall Report

- ASIIS Reminder/Recall Reports
 AIPO Train course
- Identify patients due/past due for vaccines
- Schedule patients
- Create letters, postcards, and mailing labels



If your ASIIS Inventory is not accurate

- Doses that have been administered to patients should not be removed from the Reconciliation page (Inventory) in ASIIS
- Troubleshoot why the doses did not decrement
 - Register for Dose Accountability Webinar in AIPO Train
 - Past Dose Accountability Webinar videos in course module
- <u>Job aid</u> to walk you through process of searching/adding/editing patient records manually in ASIIS

Mark doses as Received in ASIIS when the doses arrive

- Required regardless what system you use to document vaccine administration (EHR, VMS, ASIIS)
- When the doses arrive, mark them as **Received** in ASIIS
 - Log into ASIIS
 - Go to Orders/Transfers> Create/View Orders> Select arrow for Inbound Order/Transfer
 - Verify the expiration date, lot number, and quantity of doses
 - ASIIS may show 12/31/2069 as a placeholder and you must change it
 - Click the **Receive** button to receive the doses into the ASIIS Inventory
- After the doses are **Received** in ASIIS, you may administer them
- If you administer doses before they are Received into the ASIIS inventory, they will not decrement from the ASIIS inventory

Order De	tails						_	
Shipped Quantity	Receipt Quantity	Rejected Quantity	Vaccine	Funding Source	Manufacturer	Lot Number	Expiration Date	Reason for Rejecting
300	300		COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose	PAN	MODERNA US,IN ✔	ABC123	12/31/2069	select
Comments			100			Tracking #		•
	-							Cancel Receive

Funding Source - PAN

- The funding source should be PAN.
- If you have an EHR, your EHR vendor should <u>send the code VXC50</u>. On the user interface side, you will select PAN when administering.
- If you select VFC, State, Private, or something else as the funding source, the doses will not decrement from the ASIIS inventory.

Communication Resources

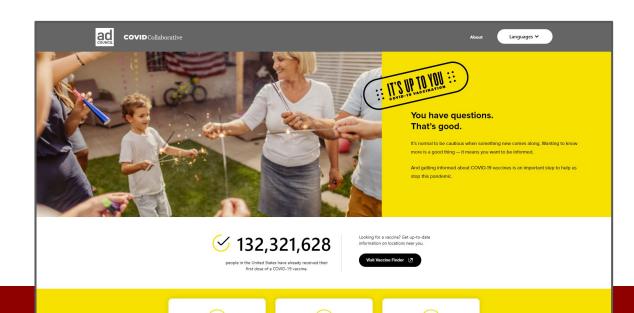
Granicus Communications (Email Updates)

The AIPO sends granicus updates (email updates) on a variety of topics including COVID-19 vaccines, ASIIS, routine vaccines, etc. This library can be accessed at any time with the above link to view previously sent updates.

Ad Council COVID-19 Vaccination Campaign: It's Up to You

getvaccineanswers.org

- Campaign site for consumers
- Answers common questions
- Provides vaccine information
- Link to Spanish site -<u>www.DeTiDepende.org</u>
- <u>Creative materials</u> that can be shared/used by providers



COVID-19 Vaccine Confidence Toolkit for Rural

Jurisdictions

- Print ads
- Posters
- Brochure
- Social media posts
- Online resource guide
- PDFs can be customized using Adobe Acrobat Pro



With the support of the <u>Delta Regional Authority (DRA)</u> and the Health Resources Services Administration's Federal Office of Rural Health Policy (FORHP), the Delta Region Community

Health Systems Development (DRCHSD)

This session will focus on identifying the four phases of

the recruitment process, distinguishing how the recruiting

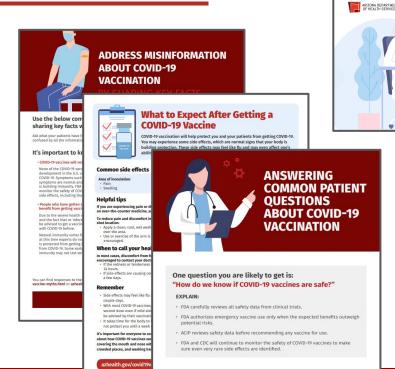
ADHS COVID-19 Communication

Resources

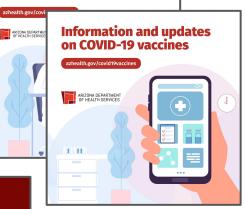
- Posters in English and Spanish (sample <u>here</u>)
- Addressing Misinformation (<u>here</u>)
- Answering Patient Questions (here)
- What to Expect After Getting COVID Vaccine (here)
- What to Expect at Your Vaccine Appointment (here)
- Vaccination Quick Answers (<u>here</u>)
- Answering Common Patient Questions (<u>here</u>)

COVID-19 Vaccine - Providers' Toolkit

Order Form to request materials for your facility



COVID-19 vaccines will not give you COVID-19.





For example, you can say:

"COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions."

HHS Video "Tell Me More About Vaccines"

The video answers commonly asked questions about the COVID-19 vaccine. The video shares why vaccines are so important and provides expert commentary and graphic illustration to help viewers understand the science of vaccine development. Tune in to hear from various experts, including Dr. Anthony Fauci (NIH), Dr. Stephen Hahn (FDA), and Dr. Robert Kadlec (ASPR), on the steps researchers and scientists are taking to develop a safe and effective vaccine. You are encouraged to add the video link to your website or promote it on social media.



FDA Emergency Use Authorization for Vaccines Explained

- What is an Emergency Use Authorization?
- Are the COVID-19 vaccines rigorously tested?
- What safety and effectiveness data are required to be submitted to FDA for an EUA request for a vaccine intended to prevent COVID-19?

CDC COVID-19 Vaccination Communication Toolkits

- For Medical Centers, Clinics, Pharmacies, and Clinicians
- For Healthcare Professionals and Pharmacists
- For LTCF Administrators and Leadership
- For Employers of Essential Workers
- For Staff of Organizations Serving Communities
- <u>Pediatric Healthcare Professionals COVID-19 Vaccination</u>
 Toolkit

The toolkit contains a variety of resources that you can use virtually or in person (with proper COVID-19 safety precautions):

- Posters
- FAQ
- Key messages
- Slide decks

Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit

Updated May 15, 2021 Print



As parents' most trusted source of information on vaccines, pediatric healthcare professionals play a critical role in helping parents/guardians understand the importance of COVID-19 vaccination and assuring them that <u>COVID-19 vaccines are</u> safe and effective.

Your strong recommendation is critical for vaccine acceptance. Tell parents/guardians how important COVID-19 vaccines are to protecting their children's health.

Remind parents that after their family is fully vaccinated against COVID-19, they may start to do some things they had stopped doing because of the pandemic.

Even if you are not administering COVID-19 vaccines, you can help parents/guardians feel confident in choosing to get their children vaccinated against COVID-19 by addressing their questions and assuring them of the safety and effectiveness of COVID-19 vaccines.

The materials on this page will help you share clear and accurate information about COVID-19 vaccines when starting or continuing conversations with parents/guardians, as well as information for those who choose not to vaccinate their child.

Only healthcare professionals enrolled as vaccination providers directly through a health practice or organization can legally store, handle, and administer COVID-19 vaccine in the United States. Learn more about becoming a COVID-19 Vaccination Provider: How to Enroll as a COVID-19 Vaccination Provider.

COVID-19 Vaccination of Minors

Patients, parents, and guardians may have questions about consent for vaccination for minors recommended to receive a COVID-19 vaccine. Learn more at: Pfizer-BioNTech COVID-19 Vaccine.

Provider Resources for Patient Conversations About COVID-19 Vaccines

How to talk to your patients about COVID-19 vaccination

CDC's Key Points to Communicate to Your Patients:

- COVID-19 vaccines are <u>safe and effective</u>.
- Individuals 12 and up are all eligible to get a COVID-19 vaccination.
- There are many locations to <u>find a COVID-19 vaccine</u>.
- Having some <u>side effects</u> after vaccination is normal.
- You are not fully vaccinated until 2 weeks after the 2nd
 dose of a two-dose vaccine or 2 weeks after a one-dose
 vaccine.

Recipient Education



Talking to Recipients about COVID-19 Vaccines

Many people have questions about the new coronavirus disease 2019 (COVID-19) vaccines. As vaccine recipients' mosttrusted source of information on vaccines, you play a critical role in helping them understand the importance of COVID-19 vaccination, as well as if and when it is likely to be recommended for them.

The materials below include proven communication strategies and tips for effectively setting expectations and addressing questions from COVID-19 vaccine recipients.



Making a Strong Recommendation for COVID-19 Vaccination



Answering Vaccine Recipients' Questions



Understanding and Explaining COVID-19 Vaccines

Background and safety information for healthcare professionals and other vaccine providers, as well as tips for explaining the vaccines to patients.

- mRNA COVID-19 Vaccines
- Viral Vector COVID-19 Vaccines

CDC COVID-19 Vaccine Web Pages for the general public

- Benefits of Getting a COVID-19 Vaccine
- How COVID-19 Vaccines Work
- <u>Frequently Asked Questions about COVID-19</u>
 Vaccination
- Understanding MRNA vaccines
- What to Expect at Your Appointment to Get Vaccinated for COVID-19
 - Translated in many languages
- When You've Been Fully Vaccinated
- Webpage COVID-19 Vaccines for Children and Teens



FAQs

FAQs

Q: If I am a VFC provider and already have an ASIIS PIN, do I still need to onboard?

• A: Yes. If a facility location wants to administer COVID-19 vaccines, they will need to onboard and sign the CDC COVID-19 Agreement. The VFC Program and the COVID-19 vaccine program are separate programs with separate signed Agreements.

Q: How do I order COVID-19 vaccines in ASIIS?

 A: Onboarded and active COVID-19 providers can follow the instructions in this job aid on how to place orders

O: Where can I find these slides?

• A: These slides can be found at azdhs.gov/covid19vaccine on the Provider Resources page. You can also find a link to the slides and the most recent recording in the Pandemic Provider Weekly Brown Bag course in AIPO Train.

THANK YOU!